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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/456,110	12/07/1999	XIA LUO	001/001	5994

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EXAMINER
HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 04/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/456,110	Applicant(s) LUO ET AL.	
	Examiner Michael J Hayes	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 45-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 45-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 August 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over DOBAK (U. S. Patent No. 6,254,626) in view of DATO (U. S. Patent No. 3,425,419). Dobak discloses a method of advancing a heat exchanger into the carotid artery of a patient for hypothermia treatment of a stroke (col. 1, lines 39-47). Dobak further discloses that blood pressure is maintained during hypothermia treatment (col. 2, lines 29-40). Dobak does not disclose introducing the heat exchanger into a central venous vein to accomplish the hypothermia treatment. Dato teaches introducing the heat exchanger into a central venous vein to induce hypothermia in a patient (col. 2, lines 40-52). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method taught by Dato in the method of Dobak in order to quickly and conveniently cool a human body.

3. Claims 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over DATO in view of FOX (U. S. Patent No. 6,090,132) and GINSBURG (U. S. Patent No. 5,486,208). Dato discloses using a catheter inserted into a central venous vein to induce hypothermia. Dato does not disclose identifying a stroke patient for hypothermia treatment or a catheter having a heat exchange balloon portion in fluid communication with flow lumens. Fox discloses that hypothermia is the most effective known therapy for stroke (1:20-33). It would have been

obvious to one of ordinary skill in the art at the time of the invention to use the step of identifying stroke patients as taught by Fox with the method of inducing hypothermia as disclosed by Dato in order to accomplish a well known effective treatment for stroke patients. Ginsburg discloses a heat exchange catheter having an elongate structure, a plurality of lumens for heat exchange fluid flow, and a heat exchange balloon to induce hypothermia via a patient's blood vessel. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Ginsburg in the device and method of Dato and Fox in order to selectively transfer heat from blood flowing through a vessel to a fluid supplied to a catheter.

4. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over DOBAK and DATO as applied to claim 1 and further in view of STEFAN (U. S. Patent No. 4,962,757). Dobak and Dato disclose the claimed invention except for a holding anchor to suturably affix the catheter to a patient. Stefan discloses a holding anchor to suturably affix the catheter to a patient (Figs. 1, 3, 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Stefan in the invention of Dobak and Dato in order to secure a catheter.

5. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over DATO, FOX, GINSBURG, and STEFAN. Dato, Fox, and Ginsburg disclose the claimed invention as discussed above in Paragraph 3 but do not disclose an anchor suture to suturably affix the catheter to a patient. Stefan discloses a holding anchor to suturably affix the catheter to a patient (Figs. 1, 3, 9). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Stefan in the invention of Dato, Fox, and Ginsburg in order to

secure a catheter.

Drawings

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the holding anchor and structure to suturably affix as recited in claims 47 and 48 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis in the specification for a holding anchor or anchor suture.

Claim Rejections - 35 USC § 112

8. Claims 47 and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in the specification of a holding

anchor or a anchor suture.

Response to Arguments

9. Applicant generally argues that there is no motivation to combine Dobak and Dato and that Dobak teaches away from the disclosure of Dato. The examiner does not agree because, although Dobak states that total body hypothermia has undesirable side effects and is difficult to administer, it is clear from the Dobak disclosure that the method of inducing hypothermia by advancing a heat exchange catheter into a central venous vein is well known in the art. In discussing the use of hypothermia to treat stroke patients Dobak discusses selected body organ cooling, but also recognizes the use of total body cooling as taught by the method of Dato. It is clear that the method recited in claim 1 is known in the prior art.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WARD (U. S. Patent No. 5,716,386) and HAYASHI (U. S. Patent No. 6,210,697) show blood pressure control during hypothermia treatment.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.

mjh
12 April 2002

MICHAEL J. HAYES
PRIMARY EXAMINER